

REMARKS

Claim 1 in this CPA application has been amended to emphasize the present invention. As pointed out on page 4 of the application, the use of a selective estrogen receptor modulator (SERM) in hormone replacement therapy (HRT) was known prior to the present invention. That fact is acknowledged in the preamble of the Jepson claims of this case. As is also known, HRT is administered to women who have gone through or are going through menopause, an event which causes infertility as a result of normal aging, i.e., the women are or are about to be infertile. It is also explained on pages 2-3 of the application, the SERMs have their own side effects. The presently claimed invention is based on improving the known HRT method using a SERM by additionally administering an agent which exhibits progestogenic activity to the woman receiving HRT in an amount effective to modulate the side effects of the SERM.

In the last Office Action in the immediate parent application, a rejection of claims 1, 2, 10, 12 and 13 as obvious under 35 U.S.C. § 103 over the combination of Young and Rodriguez was advanced. It is respectfully submitted that such a rejection should not be made in this CPA.

The Young reference teaches the use of a SERM in HRT. Accordingly, Young simply teaches the method which is being improved in the present invention, i.e., the method set forth in the preamble of the instant claims. There is no teaching or suggestion of combating the side effects of the SERM in this reference. Since there is no teaching or suggestion the side effects of the SERM, there is also no motivation to address them.

The Rodriguez reference is concerned with preventing the development of ovarian cancer by administering progestin products either alone or in combination with other agents. Rodriguez does refer to HRT twice but in each instance, distinguishes what is being done from HRT. Thus, at column 4, lines 45-47 it is stated that "the

present invention comprises . . . a regimen that is different from that currently used for hormone replacement therapy", and that teaching is reiterated at column 7, lines 13-26. Superposing an aspect of Rodriguez on a HRT method is clearly contrary to the explicit teachings of this reference.

The Office asserted in the parent application that it would be obvious to use a progestin in connection with HRT in order to achieve the beneficial effect of preventing the development of ovarian cancer. That, it is respectfully submitted, is a hindsight justification for the proposed combination. Retrospectively justifying a combination once known is easy but Section 103 requires the combination be obvious prospectively. There is clearly no prospective motivation for the proposed combination, particularly since Rodriguez explicitly excludes HRT.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. According, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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